# EXHIBIT E

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

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| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | ) | M.D.L. No. 1456<br>Civil Action No. 01-12257-PBS<br><br>Judge Patti B. Saris |

# REPORT OF INDEPENDENT EXPERT

PROFESSOR ERNST R. BERNDT

TO JUDGE PATTI B. SARIS

FEBRUARY 9, 2005

administered drugs to the bundle of payor payments to medical/physician providers for dispensing and administering drugs. Although the phenomenon of bundling ingredient cost and dispensing fee reimbursements to pharmacies to incentivize them to dispense generic drugs has apparently enabled both pharmacy and payer to benefit, for self-administered Medicare Part B drugs the bundling of ingredient cost and administration services into an AWP-based reimbursement has raised considerably more difficult and challenging issues, issues on which payer and provider are finding it more difficult to reach agreement. While I will not reproduce the histories here, it is also quite clear that knowledgeable observers understood that physicians were able to purchase many of the Medicare Part B outpatient drugs at acquisition costs considerably less than AWP.[140,141]

98. Physicians administer drugs not only to Medicare Part B patients, but also to non-Medicare patients, such as under age 65 individuals requiring nebulizers, or under-65 patients diagnosed with and treated for cancer. Commercial carriers typically negotiate reimbursements/payments with physician practices or other provider networks when such physician-administered drug services are provided. The record in this case is unsettled to date as to whether those payments to physicians for physician-administered drugs and related services are based predominantly on AWP (as has been argued by Plaintiffs' experts Raymond Hartman[142] and Professor Meredith Rosenthal[143]) or instead are negotiated as part of the overall

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[140] For a review of some of the public studies, see MedPAC [2003], *supra*. Also see Attachment B to this report.

[141] Earlier in this report I quoted Professor Kolassa's [1994a] description of the perverse incentives facing any given generic manufacturer to attempt unilaterally to set its ex-factory prices close to its AWPs. While that description written quite some time ago, Plaintiffs have provided evidence that this incentive structure persists to the present today – at least in the context of physician-administered drugs; see, for example, the Dey Complaint (Dey is a generic specialty drug manufacturer) cited in P*laintiffs' Reply to Schering-Plough Group's Individual Memorandum in Opposition to Class Certification*, December 17, 2004, pp. 9-10.

[142] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification,* September 3, 2004, Attachment D, p. 10, citing the Dyckman & Associates 2002 report, which reported AWP reimbursement rates from commercial carriers varying between 85% and 115% of AWP.

physician fee schedule involving both drugs and services, based on "charges" rather than on costs (as has been argued by Defendants' Expert Steven J. Young[144]). While I note the controversy here, I will not comment on it further at this time.

99. It is important to note, however, that very important differences exist between self-administered and physician-administered drugs involving their distribution and management. One of the more important differences concerns distribution logistics. Many physician-administered drugs are sold by manufacturers directly to physicians or to hospitals' outpatient departments; group purchasing organizations ("GPOs") often act as intermediaries between manufacturers and physicians/hospitals, although typically GPOs, like non-mail order PBMs, do not actually take title to the drugs.[145] Providers receive reimbursement for the drug as well as compensation for the services of administering the drug. Less frequent is the situation when specialty and retail pharmacies distribute the products directly to patients. In some cases pharmacies may provide the drug to physicians, but then receive reimbursement directly from the health plan/insurer, thereby eliminating the physician reselling transaction.[146]

100. A second major difference between self-administered and physician-administered drugs involves the fact that while PBMs have become crucial agents in impersonally and efficiently electronically adjudicating billions of prescriptions for self-administered brand and generic drugs, thereby serving as a behind-the-scenes invaluable intermediaries, the rapidly

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[143] Written tutorial of Meredith Rosenthal, Ph.D., before Judge Patti B. Saris, December 6, 2004, p. 10, citing the same Dyckman & Associates 2002 report, quoting it as saying "that most plans use a pricing formula that is in the range of 90% to 100% AWP, with the average at 98% of AWP."

[144] *Sur-Reply of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, January 20, 2005, pp. 6-21, and accompanying appendices.

[145] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification,* September 3, 2004, Attachment C, p. 5; Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Introduction, Final Report, Contract #500-00-0049, Task Order 1, Cambridge, MA: Abt Associates Inc., August 30, 2004, pp. 10-11.

[146] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification,* September 3, 2004, Attachment C, p. 5.